trated with an example that highlights pitfalls involved with more simplistic approaches.

PRM63

CLOSING THE GAP BETWEEN THE FORMULATION AND IMPLEMENTATION OF CLINICAL PRACTICE GUIDELINES BASED ON EVIDENCE

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OBJECTIVES: To describe the theoretical approach suggested to close the gap between recommendations and implementation of clinical practice guidelines (CPG's) in Colombia, called harmonization of CPG's with Public Policy. **METHODS:** Perspective paper. A theoretical approach is suggested to harmonize CPG's recommendations with public policy. **RESULTS:** Public policies often don't get the desired results, because there is a gap between the decision and the reality. There is a conceptual and temporal separation between policy formulation and implementation of decisions, CPG's are tools to improve quality in the delivery of health services. However a process od harmonization between recommendations and implementation with public policy is requested. For this a process of three phases should be developed: 1) To do a review of existing regulations on health and on the specific issue of the CPG to harmonize the current policy with recommendations and identify barriers to the implementation process; 2) To adjust recommendations of CPG's to eliminate the barriers encountered with the standards; 3. To state a negotiation process with all actors involved in the implementation of the CPG's at different levels of care, to generate commitment with them, proposals for changes in policy and / or administrative, and if it is necessary, to remove barriers **CONCLUSIONS:** Harmonization of CPG's with public policy is a fundamental tool to improve their implementation. Three phases are proposed. Negotiation could be the most important one.

PRM64

SOCIETAL PERSPECTIVE IN ECONOMIC EVALUATION: CONFUSIONS AND HIRA'S RECOMMENDATION

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BACKGROUND: Current HIRA's guideline recommends that economic evaluation (EE) analysis should take societal perspective, yet the inconsistency in current guideline has been noted by the industry side. The purpose of this study is to review current theoretical trends and discuss the needs of updating HIRA's current recommendations. **METHODS:** To identify the needs of EE guideline revision, HIRA has reviewed currently updated foreign EE guidelines, and discussed recent theoretical trends. In addition, survey results from pharmaceutical companies as well as decision makers regarding current recommendation were considered. Experts meetings and working group meetings with industry people were held to share each party's perspectives. **RESULTS:** Pharmaceutical industry suggested that current recommendation of taking societal perspective while submitting indirect cost (especially productivity cost) separately is confusing. Canada (CADTH) has recently updated its perspective as "publicly funded health care system", and UK (NICE) has recommended to take payer(NHS and PSS)'s perspective. Inconsistencies in societal perspective have also discussed in previous studies and ISPOR consensus paper. **CONCLUSIONS:** Given that EE guideline should provide clear minimum standards for submission parties, a need to clarify current "societal" perspective has been agreed by relevant parties. "Limited" societal perspective has been proposed to reduce unnecessary confusions while reflecting current practice patterns.

PRM65

PREVALENCE-BASED VERSUS INCIDENCE-BASED ECONOMIC EVALUATIONS FOR THE ASSESSMENT OF NEW HEALTH CARE INTERVENTIONS

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OBJECTIVES: To compare the usefulness to decision makers of prevalence-based versus incidence-based economic evaluations of new health care interventions **METHODS:** Comparison of evaluation methods by: population included, time horizon, outcomes measured, adherence to economic principles, and usefulness to decision makers. **RESULTS:** An incidence-based economic evaluation follows a disease cohort for the duration of the disease and estimates discounted costs and health gains with alternative interventions. The cost-effectiveness ratio is based on individual utility maximization and provides information to decision makers about the efficiency of a new healthcare intervention compared to societal willingness to pay for health gains. It does not estimate annual budget impacts. It generally does not capture indirect effects on the population. A prevalence-based economic evaluation provides estimates of costs and health benefits for the total population for one year or cumulated over a longer time horizon. The estimated ratio of cumulative costs and health benefits is not based on economic principles. Appropriate threshold values for these ratios are those based on a percentage of Gross Domestic Product as recommended by the World Health Organization. The prevalence-based cost-effectiveness ratio provides information to decision makers on the affordability of the intervention and the value for money over the selected time horizon. A prevalence-based analysis can take into account indirect effects of health care interventions and is, therefore, frequently used for economic evaluations of vaccine programs. **CONCLUSIONS:** Prevalence-based economic evaluations might be of greater use to health care decision makers than incidence-based evaluations because, in addition to estimates of value for money, they provide estimates of affordability and allow comparison of all types of health care interventions. Threshold values based on economic principles, however, are not applicable for ratios generated using the prevalence-based approach.

DISEASE-SPECIFIC STUDIES

DIABETES/ENDOCRINE DISORDERS – Clinical Outcomes Studies

PDB1

COMPARING HYPOGLYCEMIA RATES FOR TYPE 2 DIABETES PATIENTS TREATED WITH SAXAGLIPTIN VERSUS SULFONYLUREA: USING CLAIMS DATA TO REPLICATE A CLINICAL TRIAL

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OBJECTIVES: A lower rate of hypoglycemia occurred in a Phase 3 trial in T2DM patients receiving saxagliptin compared to glipizide (sulfonylurea (SU)) added to metformin. The clinical trial included patient-reported and physician-reported hypoglycemia events. The objective of this study was to compare the rates of hypoglycemia events that required medical attention in actual clinical practice. **METHODS:** *MarketScan* health care claims data was used to identify patients who initiated saxagliptin or SU. During the 6 months prior to initiation, patients were required to have a prescription (Rx) for metformin and no saxagliptin, SU, or other diabetes Rx. Patients were followed for 4 months to assess the rates of hypoglycemia. During follow-up, patients were required to have at least one more metformin Rx and one additional saxagliptin/SU Rx and no other diabetes Rx. A hypoglycemia event was defined as a diagnosis of hypoglycemia on an outpatient or emergency room claim or principal diagnosis on a hospital claim or an outpatient glucagon injection. SU patients were matched to saxagliptin patients (5 to 1) using propensity scores. The rate ratio was further adjusted for covariates that were not balanced between the matched cohorts using a Poisson regression model. **RESULTS:** There were 1,567 saxagliptin, 21,025 SU, and 7,835 propensity-matched SU patients. The rate of hypoglycemia in the saxagliptin cohort was 1.74 per 100 PY versus 6.68 in the SU cohort (rate ratio 0.31, 95% CI: 0.14 – 0.60) and 4.45 per 100 PY in the matched SU sub-group (rate ratio 0.39, 95% CI: 0.17 – 0.77). After multivariate adjustment, the rate ratio was 0.37 (95% CI: 0.19 – 0.74). **CONCLUSIONS:** In real world practice, as was demonstrated in a randomized controlled trial, saxagliptin patients had a lower risk of hypoglycemia than SU when added to metformin.

PDB2

VITAMIN B AND/OR ITS DERIVATIVES FOR DIABETIC KIDNEY DISEASE: A SYSTEMATIC REVIEW AND META-ANALYSIS

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OBJECTIVES: To assess the benefits and harms of vitamin B and/or its derivatives in patients with diabetic kidney disease (DKD). **METHODS:** We searched the Cochrane Renal Group's Specialized Register CENTRAL; MEDLINE OVID SP; Hand searching of renal journals and conference proceedings; EMBASE OVID SP; the International Clinical Trials Register (ICTRP) Search Portal & ClinicalTrials.gov. Randomized controlled trials (RCTs) comparing vitamin B and/or its derivatives with placebo, no or active treatment, in patients with DKD were included. **RESULTS:** Out of 56 identified studies, four studies were found to be suitable for inclusion. A total of 745 participants were randomized to either vitamin B derivatives (benfotiamine (300 mg TID), thiamine (300 mg OD), vitamin B12 (500 mg OD), folic acid (2.5 mg OD), vitamin B6 (25 mg OD)) or placebo or active control. Treatment duration ranged from 3 months to 36 months. We found that none of those derivatives improved kidney function: improved creatinine clearance (Mean difference (MD) 2.00, 95% CI -21.78 to 25.78, P = 0.87), decreased serum creatinine level (MD 1.00, 95% CI -7.88 to 9.88, P = 0.83), reduce level of urinary albumin excretion level (MD: -16.75, 95% CI -103.44 to 69.94, P = 0.70), improved the glomerular filtration rate (MD: -7.00, 95% CI -22.33 to 8.33, P = 0.37) significantly compared to placebo or active control. In addition, we found that risk of myocardial infarction, stroke, revascularization, and all-cause mortality, in the B-vitamin combination therapy group was increased (Risk Ratio 1.85, 95% CI 0.99 to 3.45, P= 0.05). We also found no significant difference between vitamin B combination therapy and control group for serious adverse events, and one or more adverse events. **CONCLUSIONS:** We did not find any improvement in kidney function, following use of vitamin B preparation. These findings require confirmation from high quality randomized trials.

PDB3

RISK OF COMPLICATIONS IN TYPE II DIABETIC PATIENTS WITH RENAL IMPAIRMENT: AN ANALYSIS OF THE RAMQ DATABASE

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OBJECTIVES: Chronic kidney disease is often associated with type II diabetes mellitus (T2DM). Patients with T2DM and chronic renal failure are at higher risk of developing hypoglycemia or metabolic acidosis. The purpose of this study was to identify treatment patterns in T2DM patients with chronic renal failure and to estimate the risk of developing complications. **METHODS:** This study examined data on patients covered by the Quebec provincial drug reimbursement program (RAMQ) who had a diagnosis of diabetes, had used a hypoglycemic agent, and had a diagnosis of chronic renal disease in the period from January 2005 to December 2010. A 1:1 control group of patients with diabetes and without renal disease, matched for age and gender, was also created. Patients' characteristics and drug utilization patterns were analyzed and the risks of experiencing hypoglycemia or metabolic acidosis were estimated. **RESULTS:** A total of 4889 patients who had a diagnosis of diabetes with chronic renal failure were included in this cohort. Aver-

age age was 69.2 years (SD=10.1) and the proportion of men was slightly higher (54.4%). The hypoglycemia incidence was higher in patients with than without renal insufficiency (10.8% vs. 3.6%; p<0.001). Similarly, the metabolic acidosis incidence was higher in patients with than without renal insufficiency (1.9% vs. 0.9%; p<0.001). Renal insufficiency in diabetic patients was associated with increased hypoglycemia [OR: 3.3 (95% CI: 2.8 – 3.9)], and metabolic acidosis [OR: 2.2 (95% CI: 1.5 – 3.2)]. **CONCLUSIONS:** A significant proportion of diabetic patients with chronic renal failure experienced hypoglycemia or metabolic acidosis. Treatment strategies for these patients that minimize the risk of these complications should be considered.

PDB4

CONDUCT OUTCOMES RESEARCH IN CHINA - ADDRESSING CHALLENGES IN DATA QUALITY CONTROL

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OBJECTIVES: In China, an estimated 90 million adults are diabetic. An out-patient clinic physician in a comprehensive hospital sees an average of 50 patients per day. Patients but not physicians maintain the medical records. Investigators are not used to electronic data acquiring systems. All these factors present challenges for conducting quality outcomes research. We recently conducted "Nationwide Assessment of Cardiovascular Risk Factors in Chinese Patients with Type 2 Diabetes", which was aimed to enroll 25000 non-institutional patients nation-wide. In order to ensure high quality and efficiency of the study, a multifaceted data quality control process was implemented and evaluated. **METHODS:** For enrolled patients who signed informed consent form, investigators were first required to report the original patient information on a "Patient Record Form" which served as source documents, and subsequently to enter the data into a web-based electronic data capture system (VitalEDC, VSRI), which performs instantaneous edit checks and generates real time data query. All investigational sites received frequent onsite monitoring and auditing when frequent data query occurred or when 50% enrollment achieved. Additionally, a 10% of the patient records at each site were randomly selected for a remote source document verification (rSDV). **RESULTS:** A total of 734 investigators from 103 hospitals across 6 regions of China participated in this study, and 25817 patients were enrolled within 8 months. Among enrolled patients, 100% the data were retrieved, 4,590,00 data records were evaluated, over 3000 unique queries were generated, only 1.5% (377 out of 25,817) of the patients' records were excluded from analyses due to unexplainable queries of pre-defined key information. **CONCLUSIONS:** The large sheer volume and rising epidemic of cardiometabolic and other chronic diseases demand well controlled epidemiological and comparative effectiveness research in China. Despite challenges, multifaceted measures of quality control could yield relatively satisfactory outcomes.

PDB5

EFFICACY AND SAFETY OF LIRAGLUTIDE 1.2MG AND EXENATIDE 10MCG TWICE DAILY IN TYPE 2 DIABETES MELLITUS: A SYSTEMTIC REVIEW AND META-ANALYSIS

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OBJECTIVES: To systematically examine the efficacy and safety of liraglutide 1.2mg once-daily and exenatide 10mcg twice daily indirectly using meta-analysis of randomized controlled trials (RCTs) involving a common comparator. **METHODS:** A systematic review of the literature and meta-analysis was conducted. PUBMED and MEDLINE (January 2000 – July 2011) were searched to identify English-language randomized trials. Keywords included type 2 diabetes, liraglutide or exenatide, and randomized controlled trials. Inclusion criteria were RCTs >12 weeks in duration, type 2 diabetes patients≥18 years old, involving liraglutide 1.2mg once daily or exenatide 10mcg twice daily. Meta-analysis was conducted for the following outcomes: change from baseline in HbA1c, systolic blood pressure, weight and the number of hypoglycemic episodes. Data were extracted and tabulated by two independent reviewers and differences were solved by consensus. 41 RCTs were identified and 16 RCTs were included for further review. Only 10 RCTs with placebo as common comparators had sufficient information and were included in the analysis. Weighted mean differences (WMD) and their 95% confidence intervals were calculated as appropriate. STATA 11.0 (StataCorp, College Station, Tex) was used to perform the meta-analysis. **RESULTS:** Liraglutide 1.2mg once daily reduced HbA1c 1.10% more than placebo (p<0.001); exenatide 10mcg twice daily reduced HbA1c 0.60% more than placebo, but not statistically significant (p=0.723); liraglutide 1.2mg reduced weight 0.18kg more than placebo (p=0.060),and exenatide reduced weight 0.53kg more than placebo (p=0.084); The rate of moderate hypoglycemia associated with liraglutide 1.2mg was 2.93% in comparison to placebo; The rate of moderate hypoglycemia associated with exenatide 10mcg was 9.22% in comparison to placebo. **CONCLUSIONS:** Indirect comparison of liraglutide 1.2mg once daily and exenatide 10mcg twice daily suggest that in comparison to exenatide 10mcg, liraglutide 1.2mg provided greater improvement in HbA1c, with fewer hypoglycemia episodes.

PDB6

ANGIOTENSIN RECEPTOR BLOCKERS AND RISK OF CARDIOVASCULAR DEATH IN PATIENTS WITH TYPE 2 DIABETES MELLITUS

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OBJECTIVES: Angiotensin Receptor Blockers (ARBs) are indicated for the prevention and treatment of kidney disease in patients with Type 2 Diabetes Mellitus (T2DM), with established efficacy for nephropathy outcomes. Randomized Controlled Trials (RCTs) have also shown the benefit of using ARBs on cardiovascular outcomes in patients with T2DM. Results from the ROADMAP trial raised concerns of increased risk of cardiovascular death with olmesartan. Currently available ARBs differ in terms of potency and surmountable versus insurmountable blockade; therefore, not all of them provide the same benefits and harms. In the absence of published direct comparative studies, however, an indirect comparison among these agents is necessary to inform clinical decision making. **METHODS:** A systematic literature search was conducted in PubMed and Cochrane Central Register of Controlled Trials through September 2011 for RCTs evaluating ARBs in patients with T2DM. Outcomes of interest were cardiovascular death, all-cause mortality, and cardiovascular morbidity and mortality. Outcomes were initially pooled using standard random-effects methods producing odds ratios (OR) and 95% confidence intervals (CI). Adjusted indirect comparisons between agents using pooled estimates were then performed using Song's method when a common comparator was available, typically a placebo. **RESULTS:** A total of 10,833 patients from 7 RCTs were analyzed. Compared to olmesartan, candesartan offered statistically significant protection against cardiovascular death (OR 0.14, 95%CI 0.03 - 0.72), while irbesartan trended towards protection (OR 0.22, 95%CI 0.05 - 1.02). No significant difference was found between candesartan and irbesartan in cardiovascular death (OR 0.64, 95%CI 0.31 to 1.34). No significant differences were found between any agents for all-cause mortality or cardiovascular morbidity or mortality. **CONCLUSIONS:** Differences in outcomes may exist between ARBs in patients with T2DM, so head-to-head clinical trials are required to confirm the findings of this adjusted indirect comparison analysis.

PDB7

EFFICACY AND SAFETY OF LIRAGLUTIDE 1.2MG ONCE DAILY IN TYPE 2 DIABETES MELLITUS: A SYSTEMATIC REVIEW AND META-ANALYSIS

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OBJECTIVES: Comparing the efficacy and safety of liraglutide 1.2mg once daily with other hypoglycemic agents in adults with type 2 diabetes through systematic review and meta-analysis of randomized controlled trials. **METHODS:** A systematic review of the literature and meta-analysis was conducted. PUBMED and MEDLINE (Jan 2000 – July 2011) were searched to identify English-language randomized control trials. Keywords included: type 2 diabetes, liraglutide, and randomized controlled trials. Inclusion criteria were: RCTs >12 weeks in duration, type 2 diabetes patients ≥18 years old, comparing liraglutide 1.2mg once daily with placebo or other active diabetic medications. Meta-analysis was conducted for the following outcomes: change from baseline in HbA1c, systolic blood pressure and weight as well as the number of hypoglycemic episodes. Two reviewers independently assessed trials for inclusion and extracted data. Differences were solved by consensus. 41 RCTs were identified and 5 RCTs met the inclusion criteria. The comparators were rosiglitazone, glimepiride, placebo and sitagliptin, and were collectively defined as the "comparators". HbA1c, weight and systolic blood pressure were analyzed as weighted mean differences (WMD), and the number of hypoglycemic episodes as relative risks (RR). STATA 11.0 (StataCorp, College Station, Tex) was used to perform the meta-analysis. **RESULTS:** In comparison to the "comparator group", patients receiving liraglutide 1.2mg reduced HbA1c by 0.54% more (95% confidence interval, CI=-0.81 to -0.28, p<0.001); weight loss with liraglutide 1.2mg was 0.54 kg more than with comparators (95% CI=-0.72 to -0.36, p<0.001); liraglutide 1.2mg reduced systolic pressure 0.14mmHg more than the comparators (95% CI=-0.22 to -0.06, p<0.001); Hypoglycemia episodes were similar between liraglutide 1.2mg and the comparators (RR=0.86, 95%CI: 0.39 to 1.93, p=0.722). **CONCLUSIONS:** Liraglutide 1.2mg once daily is effective in glycemic control, has the advantage of promoting weight loss and reducing systolic blood pressure versus the comparators for treating type 2 diabetes.

PDB8

THE EFFECT OF DAPAGLIFLOZIN ON HEDIS PERFORMANCE MEASURES OF HBA1C IN PATIENTS WITH TYPE 2 DIABETES MELLITUS

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OBJECTIVES: Healthcare Effectiveness Data and Information Set (HEDIS) measures are used to rate health plan performance; HEDIS quality of diabetes care measures include glycated hemoglobin (HbA1c) categories <7% or <8%, which define good control, and >9%, which defines poor control. Dapagliflozin, a sodium glucose cotransporter 2 inhibitor, is under clinical development for the treatment of type 2 diabetes mellitus (T2DM). We assessed the effect of dapagliflozin on achieving HbA1c outcomes by HEDIS categories. **METHODS:** Pooled data for dapagliflozin 10 mg/day (N=1066) vs placebo (N=1257) from nine 24-week, phase 3, randomized, placebo-controlled trials in patients with T2DM, including monotherapy (NCT00528372, NCT00736879) and add-on to metformin (NCT00528879, NCT00855166), glimepiride (NCT00680745), pioglitazone (NCT00683878), or insulin (NCT00673231), or initial combination with metformin (NCT00859898, NCT00643851) trials, were analyzed. Adjusted mean change in HbA1c from baseline to week 24 with dapagliflozin vs placebo was determined for patients with baseline HbA1c of <8%, ≥8% to<9%, and ≥9%. Additionally, the proportions of patients achieving HEDIS HbA1c categories of <7%, <8%, and >9% were assessed. **RESULTS:** Placebo-subtracted adjusted mean changes in HbA1c (95% CI) at 24 weeks with dapagliflozin were −0.45% (−0.56%, −0.33%), −0.62% (−0.75%, −0.48%), and −0.78% (−0.93%, −0.63%) for patients with baseline HbA1c <8%, ≥8% to<9%,